FACT SHEET
Onychomycosis

hallux

ONYCHOMYCOSIS AND ITS SYMPTOMS

- Onychomycosis (toenail fungus) is primarily a fungal infection of the toenail bed and may also involve the toenail plate. There are three major signs or symptoms of onychomycosis:
    1. Hyperkeratosis—as the infection progresses the toenail becomes thicker
    2. Discoloration—the toenail becomes yellow or yellowish brown in appearance
    3. Onycholysis—the nail plate begins to lift off or separate from the nail bed
- If left untreated, onychomycosis may spread throughout the nail unit and often to adjacent toes.

WHO IS AT RISK FOR ONYCHOMYCOSIS?

- Approximately 35 million Americans suffer from onychomycosis.
- The prevalence of onychomycosis substantially increases with age. The prevalence of fungal nail infections was 0.7% in patients younger than 19 years of age, 3.1% in ages 20-39, 9.5% in ages 40-59, and 18.2% in ages 60-79.[1]
- Risk factors include age, poor circulation, diabetes, immunocompromised persons, toenail trauma, and exposure to communal areas such as swimming pools, showers, locker rooms and gyms.

HOW DO YOU GET ONYCHOMYCOSIS?

- Toenail fungus can be contracted from exposure to a range of environments, such as gym floors or swimming pools, which make it easy for the fungus to get under the nail and into the nail bed.
- Socks and shoes create a warm and moist environment for the fungus to grow.

CURRENT ONYCHOMYCOSIS TREATMENTS

- There are two primary treatments for onychomycosis today:
    1. Oral medication
    2. Topical medications in liquid form
- Both methods are challenged: Orals are associated with systemic side effects like liver toxicity and topicals result in low cure rates and require self-application every day for twelve months or more.

Oral Medication Efficacy and Issues

- Currently terbinafine hydrochloride in oral form (Lamisil®) is the most common treatment for onychomycosis. These 250 mg tablets are taken once daily for 12 weeks. The reported complete cure rate from a 90-day treatment course is 38%.
    - Drawbacks include: Serious systemic adverse effects such as liver failure (periodic liver function testing is required while receiving oral terbinafine treatment)
    - Drug interactions with other systemic medications the patient may be taking
    - Patient compliance - tablets must be taken daily for 12 weeks

Topical Treatment Efficacy and Drawbacks

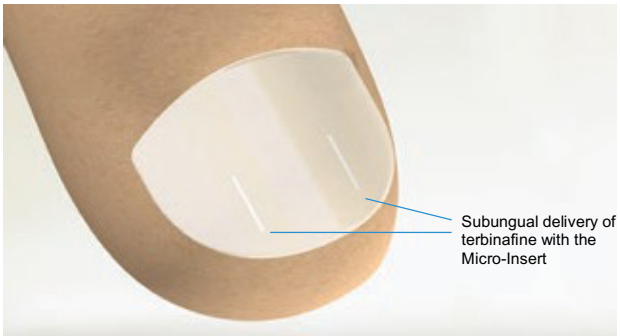
- Three major topical treatments are currently on the market.
- Reported efficacy ('complete cure') with topical treatments are:

Product	Complete Cure Rate	Source
Jublia®	15.2% to 17.8%	Package Insert
Kerydin®	6.5% to 9.1%	Package Insert
Penlac®	5.5% to 8.5%	Package Insert

- Complete cure rates with topical treatments are low because:
  - The toenail fungus is not killed—current topical treatments are fungistatic meaning that the medicine only "arrests" (slows) the growth of the fungus
  - Access to the toenail bed is challenging—the active ingredient is unable to penetrate the nail plate in adequate concentrations to reach the nail bed infection site and kill the fungus
  - Patient compliance is poor—topical products have to be applied to the toenail daily for 12 months or longer and typically patients cannot use nail polish to cover up the ugly toenail. Few patients finish the treatment course

THE HALLUX APPROACH TO ONYCHOMYCOSIS TREATMENT

- Hallux is focused on safely treating onychomycosis non-systemically with a highly effective topical subungual dosage form.
- The Company's innovative subungual approach (under the nail) is designed to conveniently and without discomfort deliver high, localized concentrations of terbinafine, a proven fungicidal (fungus-killing) drug, directly to the site of infection with little to no systemic absorption.
- Subungual therapy is designed to eliminate concerns associated with oral medications including:
  - 100% patient compliance – the subungual topical is administered by a physician in a few quick and simple in-office procedures and patients do not have to take any additional onychomycosis drugs over the 12-month period it takes to regrow a new clear disease-free nail.
  - Risk of liver toxicity and drug-interactions—with subungual topical therapy, these risks are greatly minimized as there is negligible systemic absorption with this localized approach.



The Hallux difference makes it possible to escape "The Cycle" and actually kill the fungus

The Hallux Micro-Insert has completed a phase 2 clinical study and is not FDA approved in the United States.

1. Gupta AK, Jain HC, Lynde CW, MacDonald P, Cooper EA, Summerball RC. Prevalence and epidemiology of onychomycosis in patients visiting physicians' offices: a multicenter Canadian survey of 15,000 patients. J Am Acad Dermatol. 2000;43:244-248.

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