

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 will infect the entire nail bed and often spreads 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 medication in liquid form
- Both methods are challenged with bioavailability—getting the drug to the site of the infection in adequate concentrations needed to kill the fungus.

Oral Medication Efficacy and Issues

- Currently terbinafine hydrochloride tablets (Lamisil®) are the most common treatment for onychomycosis. These tablets are taken orally once-a-day for 12 weeks in most cases. The reported complete cure rate is about 38% at one year.
- Issues 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 Issues

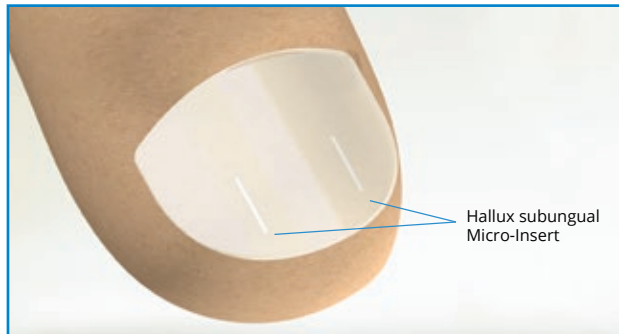
- Three major topical treatments are currently on the market.
- Reported efficacy ('complete cure') with topical treatments is under 20% including:

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 believed to be low because:
 - The toenail fungus is not killed—current topical treatments are fungistatic meaning that the treatment only “arrests” (slows) the growth of the fungus
 - Access to the toenail bed is challenging—the active ingredient is unable to penetrate the toenail in adequate concentrations at the site of infection in the nail bed
 - Patient compliance is poor—liquid medication has to be applied to the toenail daily for 12 months and patients cannot use nail polish to cover up the ugly toenail

THE HALLUX APPROACH TO ONYCHOMYCOSIS TREATMENT

- Hallux is focused on effectively treating onychomycosis non-systemically with a biodegradable Micro-Insert.
- Our 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 negligible systemic absorption.
- Subungual delivery is designed to eliminate concerns associated with oral medications including:
 - 100% patient compliance—the Micro-Insert is placed during a simple in-office procedure and patients do not have to take any additional onychomycosis drugs during treatment course
 - Risk of liver toxicity and drug-interactions—with Hallux, these risks are greatly minimized as there is negligible systemic absorption with subungual delivery of the Micro-Insert



The Hallux difference makes it possible to safely and effectively kill the fungus.

The Hallux Micro-Insert (drug/device delivery) is in clinical studies and not FDA approved in the United States.

Jublia® is a registered trademark of Valeant Pharmaceuticals International, Inc. or its affiliates.

KERYDIN® is a registered trademark of Anacor Pharmaceuticals, Inc.

Penlac® is a registered trademark of Valeant Pharmaceuticals International, Inc. or its affiliates.

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.

FOR MORE INFORMATION:

Mark Taylor, CEO
Hallux, Inc.
949.637.4656 or 800.380.9150
mark@halluxinc.com

